K042225

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510(k) Summary of Safety and Effectiveness
ACMI Corporation
ACMI® INVISIO ICN

General Information

Manufacturer:	ACMI Corporation 136 Turnpike Rd. Southborough, MA 01772-2104
Establishment Registration Number:	2020483
Contact Person:	Terrence E. Sullivan Director, Regulatory Affairs
Date Prepared:	August 16, 2004

Device Description

Classification Name:	Endoscope and accessories (21 CFR 876.1500), Class II Surgical camera and accessories (21 CFR 878.4160), Class I
Trade Name:	ACMI® INVISIO ICN
Generic/Common Name:	Endoscope, Video Camera and accessories

Predicate Device

ACMI® ECN Video CystoNephroscope System	K030960

Intended Uses

The ACMI® INVISIO ICN (ICN) Digital Flexible CystoNephroscope System (which includes the ICN scope and Controller) is intended for use to examine body cavities, hollow organs and canals in the body, in the urinary tract, and can be used percutaneously to examine the interior of the kidney; and, using additional accessories, can be used to perform various diagnostic and therapeutic procedures.

Product Description

Like the predicate ACMI® Electronic Video CystoNephroscope (ECN) System, the ACMI® INVISIO ICN (ICN) is a flexible endoscope that incorporates CMOS (complimentary medical oxide semi-conductor) sensor technology to generate an image. The ICN can be introduced either through the urethra into the bladder or through a percutaneous tract into the abdominal cavity or kidney.

The ICN incorporates the same basic video imaging technology located in the endoscope as the predicate device. There is a miniature CMOS sensor located in the distal tip, wiring running through the endoscope shaft, a printed circuit board (PCB), a light-emitting diode (LED) light source located in the handle, and an electrical cord that connects the endoscope to the Camera Control Unit.

Like the predicate device, the ICN uses the same Camera Control Unit (CCU) that contains printed circuits boards (PCBs), software, power supply and power cables to process and display the images transmitted by the camera.

This Special 510(k) proposes modifications in the proximal handle design, a reduction in flexible shaft outer diameter, elimination of the secondary active deflection mechanism, and a minor software algorithm modification for the ACMI® INVISIO ICN. The indications for use, principles of operation, working channel length and diameter of the ACMI® INVISIO ICN remain the same as in the predicate device.

Summary of Safety and Effectiveness

The proposed modifications for the ACMI® INVISIO ICN, as described in this submission, are substantially equivalent to the predicate device. The proposed modification in design specifications, performance specifications, dimensional specifications, and software specifications are not substantial changes or modifications, and do not significantly affect the safety or efficacy of the devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 0 2004

Mr. Terrence E. Sullivan
Director, Regulatory Affairs
ACMI Corporation
136 Turnpike Road
SOUTHBOROUGH MA 01772-2104

Re: K042225
Trade/Device Name: ACMI® INVISIO ICN
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Product Codes: 78 FAJ and FGA
Regulation Number: 21 CFR §878.4160
Regulation Name: Surgical camera and accessories
Product Code: 79 FWF
Regulatory Class: II
Dated: August 16, 2004
Received: August 17, 2004

Dear Mr. Sullivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Device Name: ACMI® INVISIO ICN K042225

510(k) Number:

Indications for use:

The ACMI® INVISIO ICN (ICN) Digital Flexible CystoNephroscope System (which includes the ICN scope and Controller) is intended for use to examine body cavities, hollow organs and canals in the body, in the urinary tract, and can be used percutaneously to examine the interior of the kidney; and, using additional accessories, can be used to perform various diagnostic and therapeutic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: __ X __ **OR** Over-the-Counter Use: _____

(Per 21 CFR 801.109)

David A. Lagorio

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042225